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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,701	01/29/2004	David K. Kovalic	38-21(53535)B	6459

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MONSANTO COMPANY (A&P)
800 N. LINDBERGH BOULEVARD
MAILZONE E2NA
ST. LOUIS, MO 63167

EXAMINER
ZHOU, SHUBO

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/767,701	KOVALIC ET AL.	
	Examiner	Art Unit	
	Shubo (Joe) Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2 and 4-13* is/are pending in the application.

4a) Of the above claim(s) *10-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2 and 4-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RCE

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/26/07 has been entered.

2. Claims 2, 4-7, and newly added claims 8-13 are presently pending.

However, new claims 10-13 are drawn to transgenic plants/seeds, belonging to the nonelected group III and are thus withdrawn from further consideration for being drawing to nonelected invention, there being no allowable generic or linking claim.

Therefore, claims 2, 4-9 are presently under consideration.

3. Applicant's arguments filed 11/26/07 in response to the previous Office action mailed 1/25/07 have been fully considered but they are not deemed to be persuasive. The following rejections and/or objections are either reiterated from the previous Office action or newly added, necessitated by applicant's amendments, and constitute the complete set presently being applied to the instant application. Rejections and/or objections not reiterated from the previous Office action are hereby withdrawn.

Claim Rejections-35 USC § 101/§ 112, First Paragraph

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 2 and 4-9 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The rejection is reiterated from the previous Office action mailed 1/25/07.

The amended claims are drawn to a recombinant polypeptide comprising an amino acid sequence of SEQ ID NO:44293, or a sequence that is at least 80%, 85%, 90% , 95%, 98%, or 99% identical with the amino acid sequence of SEQ ID NO:44293 or a fragment thereof. The claimed polypeptide is not supported by a specific and substantial asserted utility because none of the uses of the polypeptide as disclosed in the specification such as those detailed on pages 10-18, etc. is specific and substantial. For example, the specification states that the claimed recombinant polypeptide is involved in one or more important biological properties in a plant, that such recombinant polypeptide may be produced in transgenic plants to provide plants having improved phenotypic properties and/or improved response to stressful environmental conditions including cold tolerance, and that in some cases, decreased expression of such polypeptide may be desired (see at least page 10). These uses are not specific for the claimed polypeptide comprising a sequence of SEQ ID NO:44293. The specification generically lists a number of possible uses for the multitude polypeptides of SEQ ID NOS: 31565-63128, but fails to assert a specific utility for the claimed polypeptide comprising a sequence of SEQ ID NO:44293, and

none of the utilities is specifically linked to the elected polypeptide. Recently, in *In re Fisher,* a case analogous to the present application, the court held that an asserted use must also show that the claimed invention can be used to provide a well-defined and particular benefit to the public and that "Fisher's claimed uses are nothing more than a 'laundry list' of research plans, each general and speculative ... ." *In re Fisher*, 76 USPQ2d 1225 1229 1230 (CAFC 2005). In the instant application, the list of uses in the specification is akin to such a research plan and does not assert a particular and well-defined benefit to the public for the claimed polypeptide comprising an amino acid sequence of SEQ ID NO: 44293.

Furthermore, the claimed polypeptide is not supported by a substantial utility. For example, the specification states that the polypeptide can be used for improving stress tolerances, e.g. cold tolerance, in plants, etc. (page 11). However, this utility depends on the activity/function of the claimed polypeptide, and on the elucidation of the association of cold tolerance therewith, which are yet to be discovered through further research. The apparent need for such research indicates that the claimed polypeptide is not disclosed as to a currently available or substantial utility. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Also in *In re Fisher,* the court, following an analysis of Nelson, 626 F.2d at 856 with regard to substantial utility, states that "it thus is clear that an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research." *In re Fisher*, 76 USPQ2d 1225 1230 (CAFC 2005). In the instant case, the application does not show

that the claimed polypeptide is useful to the public as disclosed in its current form, but that it may prove useful at some future date after further research.

Additionally, neither the specification as filed nor any art of record discloses or suggests any property or activity for the polypeptide comprising an amino acid sequence of SEQ ID NO:44293 such that another non-asserted utility would be well established for the claimed polypeptide.

While it is noted that the specification in Table 1 indicates that the polypeptide of SEQ ID NO:44293 shares sequence homology with the sequence of GENBANK accession number gi29150380, which appears to encode a synaptobrevin-like protein in *Oryza sativa*, one of skilled in the art would have reasonable doubt that the polypeptide of SEQ ID NO:44293 would indeed be a synaptobrevin-like protein for the following reasons:

Firstly, the sequence of gi29150380 is a sequence directly submitted to the GENBANK and the function of the sequence appears to be proposed based on sequence comparisons with other sequences. See the enclosed printout of GENBANK accession No. AAO72389, which is also referred to as gi29150380.

Secondly, it would have been well known in the art that sequence similarity alone does not reliably correlate to identical or even similar biological activities. For example, it would have been well established in the art that even a single nucleotide or amino acid residue change or mutation in a sequence of a biomolecule would be sufficient to destroy the entire function of the biomolecule in many instances. Thus, in the absence of factual evidence characterizing the structural and functional aspects of the biomolecule, the effects of these changes would largely

unpredictable as to which ones would have a significant effect and which ones would be silent mutations having no effect. The prior art cannot *unambiguously* assign function to an unknown gene or protein purely based on sequence homology comparisons. The following example demonstrates that assignment of a known function to a metabolic gene based on homology comparisons alone provides improper and erroneous functional assignment (see the homology-based methods of functional assignment of Everett et al., Nature Genetics *17*, 411-422, **1997** in light of the experimental conclusions of Scott et al., Nature Genetics *21*, 440-443, **1999**). Everett et al. disclose a homology-based functional assignment to a putative, mutated sulfate transporter gene (PDS; which encodes "pendrin") identified through positional cloning in Pendred syndrome populations. The homology-based searches were carried out using BLAST and PSI-BLAST with commercial databases using the human pendrin clone as the query sequence. The conclusions of Everett et al. based upon the homology comparisons were that pendrin was a transporter of sulfate because it shared sequence homology with known sulfate transporter. The experimental studies by Scott et al., however, clearly demonstrate that pendrin, while having 29% homology to the rat sulfate-ion transporter encoded by *Sat-1*; 32% homology to the human diastrophic dysplasia sulfate transporter *DTD*; and 45% homology to the human sulfate transporter down-regulated in adenoma encoded by *DRA*, is actually not a transporter of sulfate, but rather that of chloride and iodine.

Thirdly, assuming *arguendo* that the polypeptide of SEQ ID NO: 44293 were indeed a synaptobrevin-like protein, one skilled in the art would have to perform further research to determine how much its activity/function is "like" synaptobrevin, and what specific and substantial utility the protein might have. It had been known that there were different members

of the synaptobrevin protein family. For instance, Raptis et al. (Journal of Chemical Neuroanatomy, Vol. 30, pages 201-211, 2005) disclosed that there were at least two isoforms of synaptobrevins: synaptobrevin/VAMP 1 and synaptobrevin/VAMP 2, which not only have different sequences, different distribution patterns, but also different specialized roles in the neurosecretory process in animals. See Abstract and page 202, left column. Thus, it would require further research to at least determine (1) what exact function the polypeptide of SEQ ID NO:44293 would have, (2) would the protein be like synaptobrevin/VAMP 1 or synaptobrevin/VAMP 2, or both, and (3) how much of its function would be "like" synaptobrevin. Once again, it is clear that the polypeptide of SEQ ID NO:44293 is not disclosed as to a currently available utility.

All the aforementioned references based upon in the above rejection have been provided to applicants in the previous Office action mailed 4/24/06.

In filing the RCE, applicant does not provide new argument with regard to the above rejection, and applicant's previous arguments filed 7/24/06 have been responded to in the final rejection mailed 1/25/07 and again in the Advisory action mailed 9/6/07.

6. The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 2 and 4-9 are rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention lacks a patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The rejection is also reiterated from the previous Office action mailed 4/24/06, and maintained for reasons set forth above.

Applicant's argument filed 7/24/06 has been fully considered and responded to in the final rejection mailed 1/25/07. No new argument has been filed.

Claim Rejections-35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 2 and 4-9 are rejected under 35 U.S.C. § 102(b) as being anticipated by Alexandrov et al. (EP 1033405 A2, September 6, 2000).

The reference and sequence alignments referred to in the following analysis have been provided to applicant in the Office action mailed 1/25/07.

This rejection is newly added, which is necessitated by the amendments filed 11/26/07.

The claims are drawn to a recombinant polypeptide comprising an amino acid sequence of SEQ ID NO:44293 or a fragment thereof, or a sequence that is at least 80%, 85%, 90%, 95%, 98% or 99% identical with an amino acid sequence of SEQ ID NO:44293 or a fragment thereof. It is reasonably interpreted that the claim is drawn to a polypeptide comprising any fragment of SEQ ID NO:44293 that is two or more amino acid residues long.

Alexandrov et al. disclose multiple polypeptides including a polypeptide, a *Zea mays* polypeptide, comprising an amino acid sequence that shares a 99.5% overall match with the full-length sequence of the instant SEQ ID NO:44293. See the sequence alignment between SEQ ID NO:44293 and the sequence of database Geneseq accession number AAG44786, which is the same sequence as that of SEQ ID NO:56142 disclosed by Alenxandrov et al. The polypeptide disclosed by Alexandrov et al. comprises a sequence that is 100% (which is at least 80%, 85%, 90%, 95%, 98% or 99%) identical with a sequence of 107 amino acid residues long: from residue number 1 to residue number 107 of SEQ ID NO:44293. See the sequence alignment between SEQ ID NO:44293 and the sequence of database accession number AAG44786. See at least pages 327-328 for the production of recombinant proteins/polypeptides.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to

reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo Zhou/

Shubo (Joe) Zhou, Ph.D.

Primary Patent Examiner